Docket No.: 3013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	
Rasmussen, et al.	Examiner: Padmanabhan, Kartic
Serial No.: 09/857,132	Art Unit: 1641
Filed: May 29, 2001	
Title: METHOD AND DISPOSABLE DEVICES FOR MICROEXTRACTION	

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Commissioner for Patents
PO Box 1450
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BRIEF ON APPEAL

This appeal is taken from a rejection of the claims of the hereinabove referenced Design Patent Application in a final Office Action mailed March 1, 2005; oral hearing is waived.

REAL PARTY OF INTEREST

The present application is not of record assigned.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences on applications related to the present application.

STATUS OF CLAIMS

Claims (See Appendix A)	Status
21-30 and 60-61	Rejected under 35 USC 112, second paragraph
21-60	Rejected under 35 USC 103(a)on the basis WO 97/25606 to Rasmussen, et al. in view of U.S. 6,164,144 to Berg and U.S. 5,615,671 to Schoonen,. et al.
61	Rejected under 35 USC 103(a) to WO 97/25606 to Rasmussen, et al. in view of U.S. 6,164,144 to Berg, U.S. 5,615,671 to Schoonen, and U.S. 5,910,448 to Atwater.

STATUS OF POST FINAL AMENDMENT

Unknown. Amended to overcome 35 USC 112 rejection submitted herewith.

CONCISE SUMMARY OF THE INVENTION

The present invention provides apparatus for carrying out liquid-liquid extraction or liquid-liquid-liquid micro extraction which includes a first container for receiving a sample

solution with the solution comprising a dissolved analyte along with a second container which comprises a liquid film that is permeable to the analyte. An acceptor solution is disposed within the second container and transport of the analyte from the sample solution through the liquid film and into the acceptor solution is enhanced. Contrary to the prior art, the present invention is directed to an apparatus device for carrying out liquid-liquid micro extraction or liquid-liquid-liquid micro extraction utilizing a membrane wall to permeate an analyte in which the analyte of interest passes through the membrane wall and is collected on an opposite side of the membrane wall than the side exposed to the sample solution with dissolved analyte.

ISSUES PRESENTED FOR REVIEW

INDEFINITENESS

The Examiner has rejected claims 21-30 and 60-61 on the basis of 35 USC 112, second paragraph.

The Appellant have submitted an amendment to overcome this rejection.

OBVIOUSNESS

The Examiner has rejected claims 21-60 on the basis of Rassmussen, et al. in view of Berg and Schoonen. Claim 61 has been rejected on the basis of Rassmussen, Berg, and Schoonen and further in view of Atwater.

GROUPING OF CONTESTED CLAIMS

No request for separate review by the Board with regard to patentability is requested.

ARGUMENT

Rejection under 35 USC 103(a) claims 21-60.

In this rejection, the Examiner states that Rasmussen, et al. teaches a device and method for liquid-liquid micro extraction with the method comprising providing a carrier, modifying the carrier, immobilizing a solvent (acceptor solution) on the carrier surface, contacting the carrier with the sample, concentrating and fixing the analyte of interest to the solvent and analyzing the carrier (emphasis added).

The Examiner further relies on Berg for teaching a method and device for solid-state micro extraction which teaches the use of a hollow fiber which acts as a "sponge".

The Examiner confirms an earlier acknowledgement that neither Rasmussen or Berg teach permeability of a hollow fiber to analyte.

The Examiner then reaches to Schoonen, et al. for teaching a process and device for monitoring analyte levels, wherein a tissue is provided with a hollow fiber having a pore size between the size of the analyte and the size of the macro molecules. A second hollow fiber is provided that is permeable for analyte but not for the macro molecules.

The Examiner concludes it would have been prima facie obvious to one skilled in the art at the time the invention was made to use a hollow fiber permeable to analyte and an acidified acceptor solution as taught by Berg and Schoonen, et al. with the invention of Rasmussen, et al.

The Examiner also stated "by using a hollow fiber, one would have been able to fill the fiber with acceptor solution rather than immobilizing the solution on the surface of the fiber."

The Appellants submit that this opinion by the Examiner, namely "one would have been able to fill the fiber...", is unsupported.

It has been established that unsupported opinions of the Examiner do not provide the factual basis required by the Supreme Court in the Deere case (148 USPQ 459, 1966) for the determination of obviousness under Section 103 (In re Wagner and Folkers, 152 USPQ 552 (CCPA 1967)). Wagner and Folkers states that neither can such (Examiner) opinions establish a "presumption" of obviousness, and that subjective opinions are of little weight against contrary evidence.

The Examiner has provided no factual support for this conclusion and a determination of obviousness must be based on facts not on unsupported generalities. In re Freed, 165 USPQ 570 (CCPA 1970).

In any event, the Examiner's statement as to "using a hollow fiber, one would have been able to fill the fiber..." is clearly a conclusion based upon the Examiner's personal opinion and one which is not supported by any stated factual basis. As enunciated by the CCPA in In re Warner and Warner, 154 USPQ 173, 178 (CCPA 1973):

> "A rejection based on Section 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from prior art...the patent office has the initial duty as supplying the factual basis for its rejection. It may not, because they doubt that the invention is patentable, resort to speculation, unfounded assumptions, or hindsight to supply deficiencies in its factual basis."

Accordingly, without factual support, the Appellants submit that the Examiner has in fact not made a prima facie case of obviousness for the rejection of claims 21-58 under 35 USC 103(a) on the basis of the Rasmussen, Berg and Schoonen, et al. references. Without further factual support, the Examiner's opinion is unfounded and accordingly a prima facie case of obviousness has not been made.

In addition, independent claims 21, 31, 42, 48, and 54 include structure and method utilizing a first and a second hollow container in which the second container is disposed within the first container and includes a membrane wall with the fibers permeable to the analyte.

The Appellants submit there is no teaching whatsoever in Rasmussen, Berg, or Schoonen for transport of the analyte from the sample solution through a membrane wall and into the acceptor solution.

While the Schoonen, et al. reference utilizes hollowed fibers, they are in fact serially connected, as clearly shown in Figure 2 as indicated by the probe 7 and enzyme reactor 8. Accordingly, even if assuming, arguendo, the Examiner's opinion that one would have been able to fill the fiber with acceptor solution, there is simply no suggestion, teaching, or hint whatsoever of utilizing a second hollow container which is disposed in a first container.

The apparatus and method claims of the present application define the invention as including transport of analyte through a membrane wall of a second hollow container disposed within the solution comprising a dissolved analyte. Further, method claims 38-51 define a process for allowing analyte equilibrium to be established between the sample solution and an acceptor solution through a membrane wall. No such method including allowing analyte equilibrium is suggested, taught, or inferred by any other references cited by the Examiner.

As early argued by the Appellants, and hereinabove noted, each of the Rasmussen and Berg references relate to structure and methods for the separation of an analyte using a surface phenomenon. Rasmussen, for example, provides for a method for immobilization of a solvent on the surface of a carrier and contacting the surface modified carrier with a material through concentrate and fix the substance to be analyzed on the surface and thereafter desorbing the concentrated substance from the carrier surface.

Berg also teaches a surface phenomenon. Although Berg discloses a needle 24, it includes a stationary phase 32 which covers an inner surface of a needle. Absorption and desorbption of

materials from a stationary phase 32 is taught.

Contrary to these disclosures, the present invention is directed to an apparatus device for carry out liquid-liquid micro extraction or liquid-liquid-liquid micro extraction utilizing a membrane wall to permeate an analyte in which the analyte of interest passes through the membrane wall and is collected on an opposite of the membrane wall than the side exposed to the sample solution with dissolved analyte.

Newly cited Schoonen, et al. teaches the profusion of a hollow fiber with a macro molecule-free profusion fluid compatible to tissue so that the analyte enters the profusion fluid through the hollow fiber. Thereafter, the profusion fluid with analyte is fed through the hollow fiber to a reactor.

This is totally contrary to the surface phenomenon used by Rasmussen and Berg hereinabove discussed.

Thus, the combination proposed by the Examiner is improper since references cannot be properly combined if the effect would destroy the invention on which one of the reference patents is based. Ex parte Hartmann, 186 USPQ 366 (PT TM Board of Appeals 1974).

In the case at hand, the Schoonen, et al. reference is based upon the profusion of a hollow fiber which is in contrast with the surface adsorption and desorbption phenomenon essential for the Rasmussen and Berg apparatus and procedures. This and of itself provides a contrary reason for combining the references.

The Appellants submit that there must be some logical reason apparent from positive, concrete evidence of record that justifies the combination of primary and secondary references. In re Regel, Bechel, and Plempel, 188 USPQ 136, 139 (CCPA 1975); Berghauser, et al. v. Dann, 204 USPQ 393, 396 (Dist. Ct. Dist. of Columbia, 1978); ACH Hospital Systems, Inc. v. Montefiore Hospital, et al., 221 USPQ 929, 933 (CAFC 1994); and In re Imperato, 179 USPQ 730, 732 (CCPA 1973).

The patent office bears the initial burden of presenting a prima facie case of patentability. In re Glaug, 62 USPQ 2d 1151, 1152 (Fed. Cir. 2002); In re Oetiker, 24 USPQ 2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 223 USPQ 785, 788 (Fed. Cir. 1994).

As hereinabove noted, there is no motivation to combine the references if the combination teaches away from the combination.

A reference may be said to teach away when a person of ordinary skill, upon reading of the reference would be discouraged from following the path set out in the reference. Such a person would be led in a direction divergent from the path that was taken by Applicant. Tech Air, 52 USPQ 2d, 1294, 1298 (Tech Air, Inc. v. Denso Manufacturing, Michigan, Inc. (US Court of Appeals Federal Circuit, 1999) citing In re Gurley, 31 USPQ 2d, 1130, 1132 (U.S. Court of Appeals, 1994)). In the case at hand, the Rasmussen and Berg references rely on a surface phenomenon of absorption and desorbption and such phenomenon is not consistent with the profusion of a fiber as taught by Schoonen, et al. Thus, there is no motivation when a proposed modification renders the reference inoperable for its intended purpose. McGinley v. Franklin Sports, Inc., 60 USPQ 2d 1001, 1010 (U.S. Court of Appeals Federal Circuit 2001).

In addition, the Examiner's opinion, as hereinabove noted, is in the nature of a "obvious to try" which is not the standard for obviousness. Rejections couched as obviousness rejections are improper because they merely reflect an opinion that would have been obvious to try a combination of modification. "Obvious to try" is not the standard under Section 103 for obviousness or motivation for combination or modification. In re O'Farrell, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

Further, assuming arguendo, that the reference may be modified or combined does not make the modification or combination obvious unless the prior art suggest the desirability of the modification or combination. In re Fritch, 23 USPQ 2d 1780, 1783 (Fed. Cir. 1992).

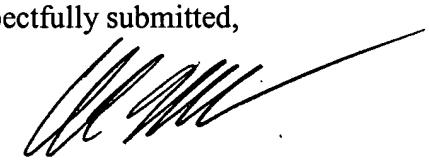
As hereinabove noted, the differences in the basic operational principles between Rasmussen and Berg and Schoonen, et al. references cannot provide any suggestion for the desirability of the combination or modification speculated by the Examiner.

Accordingly, in view of the arguments hereinabove set forth, the Appellants submit that the Examiner has not made a prima facie case of obviousness for the rejection of claims 21-60 under 35 USC 103(a) on the basis of the Rasmussen, Berg, and Schoonen, et al. references.

With regard to claim 61 the Appellant resubmits herewith the argument presented hereinabove.

In view of the arguments hereinabove set forth, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reversal of the Examiner's decision is respectfully requested.

Respectfully submitted,



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APPENDIX A

CLAIMS ON APPEAL

21. An apparatus for carrying out liquid-liquid micro extraction or liquid-liquid-liquid micro extraction, said apparatus comprising:

a first container for receiving a sample solution, the solution comprising a dissolved analyte;

a second container, that is hollow, disposed within said first container and having a membrane permeable by the analyte;

an acceptor solution disposed within the second container; and

means for enhancing transport of the analyte from the sample solution, through the membrane wall and into said acceptor solution.

22. The apparatus according to claim 21 wherein said membrane is a liquid membrane.

23. The apparatus according to claim 22 wherein said liquid membrane comprises 1-octanol.

24. The apparatus according to claim 21 wherein the second container is a tubular microporous fibre.

25. The apparatus according to claim 24 wherein the tubular fibre has a closed end and a open end for receiving and removal of said acceptor solution.

26. The apparatus according to claim 24 wherein the tubular fibre has two open ends for receiving and removal of said acceptor solution.

27. The apparatus according to claim 26 wherein the tubular fibre comprises a polymer.

28. The apparatus according to claim 21 wherein said first container has a volume of V_s,

said second container has a volume of V_a and a ratio of V_s to V_a is ≥ 50.

29. The apparatus according to claim 28 wherein V_a is between about 1µl and about 50µl.

30. The apparatus according to claim 21 wherein said acceptor solution has a pH for ionizing the analyte to prevent ionized analyte from passing from said acceptor solution through the membrane wall and into the sample solution.

31. An Apparatus for carrying out liquid-liquid micro extraction or liquid-liquid-liquid micro extraction, said apparatus comprising:

a first container;

a sample solution disposed in said first container, said sample solution comprising a dissolved analyte;

a second container, that is hollow, disposed within said sample solution and having a membrane wall with fibre pores permeable by the analyte;

an acceptor solution disposed within the second container, said membrane wall enabling analyte equilibrium to be established between said sample solution and said acceptor solution.

32. The apparatus according to claim 31 further comprises a liquid membrane disposed in said fibre pores.

33. The apparatus according to claim 32 wherein said liquid membrane comprises 1-octanol.

34. The apparatus according to claim 31 further comprising means for accelerating analyte equilibrium between said sample solution and said acceptor solution.

35. The apparatus according to claim 31 wherein the second container is a tubular microporous fibre.

36. The apparatus according to claim 35 wherein the tubular fibre has a closed end and an open end for receiving and removal of said acceptor solution.

37. The apparatus according to claim 35 wherein the tubular fibre has two open ends for receiving and removal of said acceptor solution.

38. The apparatus according to claim 37 wherein the tubular fibre comprises a polymer.

39. The apparatus according to claim 31 wherein said first container has a volume of V_s, said second container has a volume of V_a and a ratio of V_s to V_a is ≥ 50.

40. The apparatus according to claim 39 wherein V_a is between about 1µl and about 50µl.

41. The apparatus according to claim 31 wherein said acceptor solution has a pH for ionizing the analyte to prevent ionized analyte from passing from said acceptor solution through the membrane wall and into the sample solution.

42. A method of liquid-liquid micro extraction, or liquid-liquid-liquid micro extraction, said method comprising the steps of:

disposing a sample solution comprising a dissolved analyte into a first container;

disposing a second container, that is hollow, into said sample solution, providing the second container with a membrane wall having fibre pores permeable by the analyte;

disposing an acceptor solution into the second container;

allowing analyte equilibrium to be established between said sample solution and said acceptor solution through said membrane wall; and

removing analyte enriched acceptor solution from said second container.

43. The method according to claim 42 further comprising the step of disposing a liquid membrane in said fibre pores before disposing said second hollow container into said sample

solution.

44. The method according to claim 42 wherein the step of disposing a second hollow container into said sample solution comprises disposing a tubular microporous fibre into said sample solution.

45. The method according to claim 44 wherein the step of disposing a tubular fibre comprises disposing a closed end fibre into said sample solution.

46. The method according to claim 44 wherein the step of disposing a tubular fibre comprises disposing a center portion of a tubular fibre having two open ends into said sample solution.

47. The method according to claim 44 wherein the step of disposing an acceptor solution into the second container comprising the step of disposing an acceptor solution having a pH for ionizing the analyte to prevent ionized analyte from passing from said acceptor solution through the membrane wall and into the sample solution.

48. A method of liquid-liquid micro extraction, or liquid-liquid-liquid micro extraction, said method comprising the steps of:

disposing a sample solution comprising a dissolved analyte into a first container;

disposing a second container, that is hollow, into said sample solution and providing the second container with a membrane wall permeable by the analyte;

disposing an acceptor solution into the second container;

enriching analyte in said acceptor solution by allowing analyte equilibrium between said sample solution and said acceptor solution through said membrane wall; and

removing analyte enriched acceptor solution from said second container.

49. The method according to claim 48 further comprising the step of disposing a liquid membrane in said fibre pores before disposing said second hollow container into said sample

solution.

50. The method according to claim 48 wherein the step of disposing a second hollow container into said sample solution comprises disposing a tubular microporous fibre into said sample solution.

51. The method according to claim 50 wherein the step of disposing a tubular fibre comprises disposing a closed end fibre into said sample solution.

52. The method according to claim 50 wherein the step of disposing a tubular fibre comprises disposing a center portion of a tubular fibre having two open ends into said sample solution.

53. The method according to claim 48 wherein the step of disposing an acceptor solution into the second container comprising the step of disposing an acceptor solution having a pH for ionizing the analyte to prevent ionized analyte from passing from said acceptor solution through the membrane wall and into the sample solution.

54. A method of liquid-liquid micro extraction, or liquid-liquid-liquid micro extraction, said method comprises the steps of:

disposing a sample solution comprises a dissolved analyte into a first container;

disposing a second container, that is hollow, into said sample solution and providing the second container with a membrane wall permeable by the analyte;

disposing an acceptor solution into the second container and providing the acceptor solution with a pH for ionizing the analyte in order to prevent ionized analyte from passing from said acceptor solution through the membrane wall and into the sample solution;

enriching analyte in said acceptor solution by allowing analyte equilibrium between said sample solution and said acceptor solution through said membrane wall; and

removing analyte enriched acceptor solution from said second container.

55. The method according to claim 54 further comprising the step of disposing a liquid membrane in said fibre pores before disposing said second hollow container into said sample solution.

56. The method according to claim 54 wherein the step of disposing a second hollow container into said sample solution comprises disposing a tubular microporous fibre into said sample solution.

57. The method according to claim 56 wherein the step of disposing a tubular fibre comprises disposing a closed end fibre into said sample solution.

58. The method according to claim 56 wherein the step of disposing a tubular fibre comprises disposing a center portion of a tubular fibre having two open ends into said sample solution.

59. An apparatus for carrying out liquid-liquid extraction or liquid-liquid-liquid micro extraction, said apparatus comprising:

a first container for receiving a sample solution, the solution comprising a dissolved analyte;

a second container comprising a liquid film that is permeable to the analyte;

an acceptor solution disposed within the second container; and

means for enhancing transport of the analyte from the sample solution, through the liquid film and into said acceptor solution.

60. The apparatus according to claim 59, wherein the liquid film comprises of a water immiscible solvent immobilized in the pores of a hydrophobic carrier, which protects it from being released.

61. The apparatus according to claim 60, wherein the hydrophobic carrier is a porous polypropylene hollow fibre.